UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PFIZER INC.,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL, and CHRISTI A. GRIMM, in her official capacity as Principal Deputy Inspector General in the Office of Inspector General for the U.S. Department of Health and Human Services,

Defendants.

20 Civ. 4920 (MKV)

MEMORANDUM OF LAW IN OPPOSITION TO PFIZER'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' CROSS-MOTION TO DISMISS THE COMPLAINT OR FOR SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

Defendants the U.S. Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as HHS Secretary, the HHS Office of Inspector General ("OIG"), and Christi A. Grimm, in her official capacity as Principal Deputy Inspector General (collectively, "Defendants" or the "Government"), by their attorney, Audrey Strauss, Acting United States Attorney for the Southern District of New York, respectfully submit this memorandum of law in opposition to Plaintiff Pfizer Inc.'s motion for summary judgment (ECF No. 34) ("Pl. Mot."), and in support of Defendants' cross-motion to dismiss Pfizer's complaint or for summary judgment. The Court should deny Pfizer's motion, and grant Defendants' cross-motion.

Pfizer fails to assert any meritorious challenge to OIG's responses to Pfizer's requests for favorable advisory opinions blessing two proposed cost-sharing subsidy programs. OIG properly declined to give an opinion as to Pfizer's proposed indirect subsidy program because OIG was directly prohibited by regulation from doing so; and as to Pfizer's proposed direct subsidy program, OIG issued an advisory opinion reasonably concluding that the program poses a high risk of fraud and abuse under the federal Anti-Kickback Statute ("AKS")—although OIG could not reach a definitive conclusion without being able to assess the program as actually implemented. Because these agency actions complied with the Administrative Procedure Act, Defendants are entitled to summary judgment on Pfizer's challenges to them.

Defendants are entitled to dismissal of Pfizer's claims that OIG's interpretation of the AKS would violate Pfizer's First Amendment rights and the Equal Protection Clause of the Fifth Amendment. The Court lacks jurisdiction over both claims, as Pfizer does not have standing to assert either one, and the First Amendment Claim is also constitutionally unripe. Moreover, Pfizer fails to state a claim under either the First or the Fifth Amendments.

In the absence of a valid claim, Pfizer asks the Court to assume the role of OIG and issue declaratory judgments wholly adopting Pfizer's factual and legal assertions and preemptively immunizing both of Pfizer's proposed cost-sharing subsidy programs against any potential enforcement activity. The Court should not do so. For the reasons discussed below, the Court either lacks any jurisdiction to provide the blanket declaratory relief that Pfizer demands, or should decline to do so under the prudential ripeness doctrine. Put simply, the Court should reject Pfizer's improper attempts to get the imprimatur from the Court that Pfizer has failed to get from OIG.

BACKGROUND[1]

A. OIG's Role in Enforcing and Providing Guidance Regarding the AKS

The Anti-Kickback Statute ("AKS") makes it illegal to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person . . . to purchase, . . . order, . . . or recommend purchasing . . . or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). As part of its mission to root out fraud against federal healthcare programs, OIG is statutorily empowered to enforce the AKS through certain administrative remedies. *See, e.g.*, *id.* § 1320a-7c (establishing the national Health Care Fraud and Abuse Control Program); *id.* § 1320a-7(b)(7) (setting forth OIG's exclusion authority). In the context of a civil settlement, OIG may also enter into a corporate integrity agreement

[1] Pfizer erroneously asserts that the facts it sets forth in its complaint and motion "are undisputed and have been adopted by the government in its September 18, 2020 Advisory Opinion." Pl. Mot. at 3 n.1. That is not correct. The Advisory Opinion does state that it relies on—in addition to other publicly available information—facts that Pfizer certified to OIG for the purpose of submitting its proposed programs for agency consideration. AR 141. ("AR" cites are references to the certified Administrative Record filed herewith.) That does not signify that the Government has adopted Pfizer's factual assertions and characterizations in this litigation.

("CIA") with an entity, outlining obligations that the entity agrees to undertake as an alternative to the severe remedy of exclusion. *See, e.g.*, *Corporate Integrity Agreement FAQs, available at* https://oig.hhs.gov/faqs/corporate-integrity-agreements-faq.asp (last visited November 16, 2020).

OIG is also charged with providing guidance to the healthcare industry regarding anti-fraud laws, including the AKS. *See* 42 U.S.C. § 1320a-7d. As relevant here, in 2005, OIG issued a Special Advisory Bulletin on Patient Assistance Programs ("PAPs") for Medicare Part D enrollees. *See* 70 Fed. Reg. 70,623 (Nov. 22, 2005) (the "2005 Bulletin"). In the 2005 Bulletin, OIG explained that "cost-sharing subsidies provided by pharmaceutical manufacturer PAPs pose a heightened risk of fraud and abuse" under the AKS. In particular, OIG noted its "concern[] about the use of cost-sharing subsidies to shield [Medicare Part D] beneficiaries from the economic effects of drug pricing, thus eliminating a market safeguard against inflated prices." *Id.* at 70,626. OIG also discussed "non-abusive alternatives available"—including "making cash donations to independent, *bona fide* charitable assistance programs." *Id.* at 70,625-26.

In 2014, OIG issued a Supplemental Special Advisory Bulletin addressing Independent Charity PAPs. *See* 79 Fed. Reg. 31,120 (May 30, 2014) (the "2014 Bulletin"). The 2014 Bulletin updated the 2005 Bulletin in light of "some of the specific risks that have come to our attention" with respect to PAPs operated by foundations. *Id.* at 31,120-21. OIG reiterated its concern that, if permitted, "the ability to subsidize copayments for their own products may encourage manufacturers to increase prices, potentially at additional cost to Federal health care programs and beneficiaries who are unable to obtain copayment support." *Id.* at 31,122.

OIG also issues advisory opinions regarding the interpretation and application of federal anti-fraud and abuse provisions, including the AKS. *See* 42 U.S.C. § 1320a-7d(b). Under the regulations that govern this process, "[a]ny individual or entity" may submit to OIG a request for an advisory opinion regarding the application of certain laws or regulations enforced by OIG to

the specific facts of an existing or proposed activity. *See* 42 C.F.R. §§ 1008.5, 1008.11, 1008.15. Advisory opinions constitute "the OIG's opinion regarding the subject matter of the request based on the facts provided to the OIG." *Id.* § 1008.43. Individuals or entities are by no means required to request an advisory opinion before engaging in a business arrangement or activity; but one benefit of doing so is that a favorable opinion protects the requestor from OIG administrative sanctions, so long as the arrangement at issue is conducted in accordance with the facts submitted to OIG (which requestors must certify are accurate). *See Advisory Opinions FAQ*, *available at* https://oig.hhs.gov/faqs/advisory-opinions-faq.asp (last visited November 15, 2020); 42 C.F.R. § 1008.38(a). This regulatory process is "[t]he only method for obtaining a binding advisory opinion regarding" the covered subject areas. 42 C.F.R. §§ 1008.51. If OIG does not issue a definitive favorable advisory opinion, that "does not mean that the [AKS] has been violated or that an enforcement action is appropriate." *See* 63 Fed. Reg. 38,311, 38,317 (July 16, 1998). The failure to obtain a favorable opinion does not mean "that an arrangement is illegal; it means only that the arrangement may pose some risk of fraud and abuse." *Id.*

B. Pfizer's 2018 Corporate Integrity Agreement

This case is not Pfizer's first encounter with OIG and the AKS. Pfizer is *currently* bound by a corporate integrity agreement ("CIA") it executed with OIG just two and a half years ago, in connection with a $23.85 million civil settlement of allegations that Pfizer "violated the False Claims Act by paying kickbacks to Medicare patients through a purportedly independent charitable foundation" that operated a PAP. *See* https://www.justice.gov/usao-ma/pr/pfizer-agrees-pay-2385-million-resolve-allegations-it-paid-kickbacks-through-co-pay (May 24, 2018), last visited Nov. 16, 2020; AR 480 ("2018 CIA"). There, the Government alleged that Pfizer "used a foundation . . . as a conduit to pay the co-pay obligations of Medicare patients taking

three Pfizer drugs"; in the case of one of the drugs, Pfizer allegedly "coordinated the time of the opening of the fund . . . with the implementation of a [drug] price increase," "saddl[ing] Medicare with extra costs" while "masking the effect of [the] price increases" on demand. *Id.* The CIA requires Pfizer to implement numerous measures to ensure that arrangements and interactions with third-party assistance programs comport with the law. AR 481. Pfizer agreed in the CIA that for five years, it would contribute to an independent charity PAP only if:

> a. . . . Pfizer has not made and shall not make . . . suggestions or requests to the Independent Charity PAP about the identification, delineation, establishment, or modification of disease state funds;
>
> b. Pfizer does not and shall not exert any direct or indirect influence or control over the Independent Charity PAP's process or criteria for determining eligibility of patients who qualify for its assistance program; . . .
>
> d. Pfizer does not and shall not provide donations for a disease state fund that covers only a single product or that covers only Pfizer's products.

Id. at 501-02. If Pfizer materially breaches the CIA, OIG can exclude it from Medicare. *Id.* at 514-15.

C. Pfizer's 2019 Requests for an Advisory Opinion Regarding Its Proposed Programs

In June 2019, Pfizer submitted a request for OIG to issue a favorable advisory opinion regarding two alternative proposed programs relating to two forms of Pfizer's drug tafamidis, which had recently been approved by the U.S. Food and Drug Administration ("FDA") for the treatment of transthyretin amyloid cardiomyopathy ("ATTR-CM"), a disease that, according to Pfizer, affects only approximately 100,000 to 150,000 Americans. AR 1, 744. Tafamidis is currently the only FDA-approved drug for the treatment of ATTR-CM, but Pfizer acknowledges that physicians have prescribed off-label two other drugs, one of which is covered under Medicare Part B, to treat ATTR-CM; non-pharmacological treatments may also be an option for some patients; and "FDA approval of a competitor therapy in 2021 is a possibility." AR 162.

Pfizer has decided to charge about $225,000 for a single year's supply of tafamidis for a single patient. AR 2, 12, 125, 696, 745. The details and consequences of Pfizer's pricing scheme for tafamidis are explained at length in the record, *see, e.g.*, AR 10-14, 87-90, 129. As noted there, a 2020 study found that tafamidis is "the most expensive cardiovascular drug ever launched in the United States." AR 152. Treating all eligible ATTR-CM patients with tafamidis would increase health care spending in the United States by over $30 billion a year. *Id.*

In a nutshell, Pfizer asserts that, under Medicare Part D's standard benefit, a certain group of "middle-class" beneficiaries afflicted with ATTR-CM would have to pay a prohibitive $13,000 in annual out-of-pocket costs for tafamidis, because they do not qualify for assistance under either the Medicare Low-Income Subsidy or Pfizer's own free drug program—under which Pfizer provides tafamidis free of cost to lower-income patients. *See See* ECF No. 1 ("Compl.") at ¶ 6; AR 9-11, 87, 144. Pfizer thus sought a favorable advisory opinion from OIG approving of, first, a direct subsidy program (the "Direct Subsidy Program") aimed at that group of Medicare Part D beneficiaries, or, in the alternative, a program in which Pfizer would provide funds to a foundation that would itself provide a subsidy to patients otherwise unable to feasibly afford tafamidis (the "Indirect Subsidy Program" and, together with the Direct Subsidy Program, the "proposed programs"). *See* AR 13, 90-91, 499-503, 746. Specifically, Pfizer asked OIG for a favorable opinion concluding that its two proposed programs did not implicate the AKS or another statute, the Beneficiary Inducement Statute ("BIS"), 42 U.S.C. § 1320a-7a(a)(5). AR 16, 760.

On August 2, 2019, OIG rejected Pfizer's June 2019 request, explaining that it would not be "able to issue an advisory opinion" in response to the request "because '[t]he same, or substantially the same, course of action is under investigation, or is or has been the subject of a

proceeding involving [HHS] or another governmental agency." AR 794. Under 42 C.F.R. § 1008.15(c)(2), OIG may not accept advisory opinion requests (or issue advisory opinions) in those circumstances. After conferring with OIG, Pfizer became aware that only its Indirect Subsidy Program was affected by the prohibition of 42 C.F.R. § 1008.15(c)(2). AR 726. A few weeks later, Pfizer submitted a new request for an advisory opinion, proposing only the Direct Subsidy Program. AR 1. OIG accepted Pfizer's new request. AR 40.

In the following months, OIG regularly communicated with Pfizer regarding its new request, including through follow-up requests for relevant information OIG needed to issue an advisory opinion, consistent with 42 C.F.R. § 1008.39. AR 41-83. In December 2019, however, OIG informed Pfizer by phone that based on its review of Pfizer's submissions, it would not issue a favorable advisory opinion regarding Pfizer's proposed Direct Subsidy Program.[2] AR 114, 726. Pfizer requested an opportunity to submit additional information, which OIG granted. AR 726. Following review of that additional information, in May 2020, OIG informed Pfizer that its conclusion regarding the Direct Subsidy Program was unchanged and that it would not issue a favorable advisory opinion. *Id.* Pfizer had the option to withdraw its request at that time, but it did not. AR 111-13, 114-22. As a result, OIG was required to draft and issue a formal, written advisory opinion. *See* 42 C.F.R. § 1008.43.

D. The Present Litigation and the Advisory Opinion

Rather than wait for that opinion, Pfizer filed this action, seeking: (1) a declaration that the proposed programs do not violate the AKS or BIS; (2) a declaration that "the application of OIG's guidance to the [Indirect Subsidy Program]" would violate Pfizer's First Amendment

[2] Generally, OIG verbally informs advisory opinion requestors if it does not intend to issue a favorable opinion, which permits requestors to revise or withdraw their request.

rights; (3) a declaration that "the application of OIG's guidance" to the proposed programs would violate the Fifth Amendment; and (4) a judgment that OIG violated the Administrative Procedure Act. *See* Compl. ¶¶ 137-68.

After Pfizer's attempt to unduly expedite the adjudication of this matter failed, *see* ECF No. 26, the parties agreed to proceed to dispositive motions, but only once OIG had issued the advisory opinion Pfizer requested on its proposed Direct Subsidy Program. *See* ECF No. 31. OIG issued its opinion on September 18, 2020. AR 141-68 (the "Advisory Opinion"). The Advisory Opinion concluded that although the Direct Subsidy Program did not implicate the BIS, it would generate prohibited remuneration under the AKS and therefore OIG could potentially impose administrative sanctions on Pfizer, "*if* the requisite intent to induce or reward referrals for, or purchases of, items and services reimbursable by a Federal health care program were present." AR 142 (emphasis added). Because the Direct Subsidy Program has not been implemented, OIG could not reach a "definitive conclusion regarding the existence of an anti-kickback statute violation," since any such conclusion "requires consideration of all of the facts and circumstances of the arrangement as implemented, including a party's intent." *Id.*

The Advisory Opinion's AKS analysis is straightforward: the Direct Subsidy Program "would operate as a *quid pro quo*—[Pfizer] would offer remuneration . . . to the beneficiary in return for the beneficiary purchasing" tafamidis. AR 154. The program appeared designed to induce "a Medicare beneficiary [who] otherwise may be unwilling or unable to purchase [tafamidis] due to his or her cost-sharing obligations, which are driven by the list price, . . . to purchase" tafamidis, leaving Medicare to "bear the costs." AR 155. OIG concluded that "no statutory exception or regulatory safe harbor" to the AKS would cover the Direct Subsidy Program. AR 156. Thus, if the program were implemented with the intent to induce these

beneficiaries to purchase tafamidis, the program could be sanctionable under the AKS. *Id.*

Next, to determine whether, in its discretion, OIG should nevertheless agree not to take future enforcement action against the Direct Subsidy Program, the Advisory Opinion examined whether the program "would pose more than a minimal risk of fraud and abuse under the" AKS. *Id.* OIG determined that the proposed Direct Subsidy Program does so: "[i]n particular, where, as here, a manufacturer offers remuneration . . . contingent on the purchase of its products, the remuneration presents many of the traditional risks of fraud and abuse that the [AKS] is designed to prevent, including increased costs to Federal health care programs . . . ; beneficiary steering and anti-competitive effects; and interference with or skewing of clinical decision making." *Id.* OIG noted that, by virtually eliminating patient cost sharing while continuing to charge the government full price, the program would remove "one of the key pricing controls . . . that Congress instituted in its design of the standard Medicare Part D prescription drug benefit." AR 158. The program thus presented "more than a minimal risk of fraud and abuse." AR 156.

ARGUMENT

I. Legal Standards

A. Motions to Dismiss Pursuant to Rules 12(b)(1) and 12(b)(6)

Pfizer bears the burden of pleading allegations sufficient to establish the Court's jurisdiction to survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(1). *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). Courts should "presume that [they] lack jurisdiction unless the contrary appears affirmatively from the record." *Renne v. Geary*, 501 U.S. 312, 316 (1991) (quotation marks omitted).

To survive a motion to dismiss under Rule 12(b)(6), a plaintiff 's complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). In considering a Rule 12(b)(6) motion, "a district court may consider

the facts alleged in the complaint, documents attached to the complaint as exhibits, and documents incorporated by reference in the complaint," "document[s] 'integral' to the complaint," and "matters of which judicial notice may be taken." *MMA Consultants 1, Inc. v. Republic of Peru*, 245 F. Supp. 3d 486, 498 (S.D.N.Y. 2017).

B. Review of Agency Action Under the APA and Rule 56

The Administrative Procedure Act ("APA") authorizes judicial review of certain final federal agency actions. 5 U.S.C. § 704. A court may "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "contrary to constitutional right." *Id.* §§ 706(2)(A), (B). APA claims must be brought within six years of the challenged agency action. *See* 28 U.S.C. § 2401(a); *Wong v. Doar*, 571 F.3d 247, 263 (2d Cir. 2009).

Judicial review of agency action under the APA is limited to the administrative record compiled and relied upon by the agency. *See, e.g.*, *Nat. Res. Def. Council, Inc. v. Muszynski*, 268 F.3d 91, 97 (2d Cir. 2001). Therefore, "summary judgment is appropriate, since whether an agency action is supported by the administrative record and consistent with the APA standard of review is decided as a matter of law." *Residents for Sane Trash Solutions, Inc. v. U.S. Army Corps of Eng'rs*, 31 F. Supp. 3d 571, 586 (S.D.N.Y. 2014); *see also* Fed. R. Civ. P. 56.[3]

1. Deferential Review of Agency Action and Statutory Interpretation

Agency actions are afforded a presumption of regularity. *Estate of Landers v. Leavitt*, 545 F.3d 98, 113 (2d Cir. 2008). In particular, "the well-reasoned views of the agencies

[3] The Government has not filed a Local Civil Rule 56.1 Statement, because Pfizer's APA claims present only legal issues regarding the lawfulness of the Government's action in light of the administrative record. *See, e.g.*, *Just Bagels Mfg., Inc. v. Mayorkas*, 900 F. Supp. 2d 363, 372 n.7 (S.D.N.Y. 2012); *Karpova v. Snow*, 402 F. Supp. 2d 459, 465 (S.D.N.Y. 2005).

implementing a statute constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance." *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001) (citations and quotation marks omitted); *see also, e.g.*, *Heckler v. Chaney*, 470 U.S. 821, 832 (1985) ("[C]ourts generally will defer to an agency's construction of the statute it is charged with implementing, and to the procedures it adopts for implementing that statute").

Here, in contrast with Pfizer's assertions, unfettered *de novo* review of OIG's actions is not the applicable standard. *See* Pl. Mot. at 8-9. OIG's interpretation of the AKS, set forth in the Advisory Opinion, is entitled to deference, even if the Advisory Opinion is not a "rule of decision." *Id.* at 8. As an agency tasked with interpreting and enforcing that statute, OIG's views receive "considerable weight" and "deference as an 'informed judgment to which courts and litigants may properly resort for guidance.'" *Zimmer, Inc. v Nu Tech Med., Inc.*, 54 F. Supp. 2d 850, 856 (N.D. Ind. 1999) (giving deference to an advisory opinion issued by OIG concerning the AKS) (citations omitted); *see also e.g.*, *Christensen v Harris County*, 529 U.S. 576, 587 (2000) (interpretations contained in formats such as opinion letters are "entitled to respect" to the extent that those interpretations have the "power to persuade").

Nor are OIG's views in the Advisory Opinion entitled to any less deference because Pfizer prematurely initiated this lawsuit while it knew its own request for the Advisory Opinion was pending. *See* Pl. Mot. at 9; *see also, e.g.*, *Lockheed Martin Corp v. Morganti*, 412 F.3d 407, 411 (2d Cir. 2005) ("[A]gency interpretations presented in litigation may still be given deference so long as they are not *post hoc* rationalizations of past agency action."). When Pfizer filed this suit, OIG had already informed Pfizer of its determination not to issue a favorable opinion, and it was drafting the Advisory Opinion. *See supra* Parts C-D (Background). Pfizer may not gain an unwarranted advantage by filing suit while the agency's work was in progress.

2. The Usual APA Remedy Is Remand to the Agency

If a court does find that a final agency action has violated the APA, by the plain language of the statute, the "usual remedy" is remand to the agency for further consideration in light of the court's ruling. *See New York v. U.S. Dep't of Commerce*, 351 F. Supp. 3d 502, 673 (S.D.N.Y. 2019), *aff'd in part, rev'd in part and remanded*, 139 S.Ct. 2551 (2019); *see also, e.g.*, 5 U.S.C. § 706(2); *FEC v. Atkins*, 524 U.S. 11, 25 (1998) ("If a reviewing court agrees that the agency misinterpreted the law, it will set aside the agency's action and remand the case"); *Guertin v. United States*, 743 F.3d 382, 388 (2d Cir. 2014) ("In the usual case, when an agency violates its obligations under the APA, we will vacate a judgment and remand to the agency"); *Am. Fed'n of Labor and Cong. of Indus. Orgs. v. NLRB*, No. 20-cv-0675 (KBJ), 2020 WL3041384, at *19, 22 (D.D.C. June 7, 2020) ("[O]nce an unlawful agency rule is set aside . . . the court remands the matter to the agency so that the agency can reconsider the rule in light of the court's ruling").

C. The Declaratory Judgment Act

The Declaratory Judgment Act gives federal courts discretion to "declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). However, the Act neither operates as an independent grant of jurisdiction, *see, e.g.*, *In re Joint E. & S. Dist. Asbestos Litig.*, 14 F.3d 726, 731 (2d Cir. 1993), nor does it create a cause of action, *see, e.g.*, *Chevron Corp. v. Naranjo*, 667 F.3d 232, 244 (2d Cir. 2012). Rather, the Act's "operation is procedural only—to provide a form of relief previously unavailable." *In re Joint E. & S. Dist. Asbestos Litig.*, 14 F.3d at 731.

Courts may exercise their discretion to *decline* to entertain a request for declaratory relief. *See Dow Jones & Co., Inc. v. Harrods Ltd.*, 346 F.3d 357, 359 (2d Cir. 2003); *Pub. Serv. Comm'n of Utah v. Wycoff*, 344 U.S. 237, 241 (1952). Indeed, courts "traditionally have been reluctant" to issue declaratory judgments where plaintiffs have challenged administrative

determinations, "unless these arise in the context of a controversy 'ripe' for judicial resolution." *See Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967) (abrogated on other grounds by *Califano v. Sanders*, 430 U.S. 99 (1977)); *see also, e.g.*, *Velvet Underground v. Andy Warhol Found. for the Visual Arts, Inc.*, 890 F. Supp. 2d 398, 403 (S.D.N.Y. 2012) ("The controversy must at all times remain "definite and concrete"). One purpose of this principle is "to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Abbott Labs.*, 387 U.S. at 148-49.

Relief under the Act is discretionary even if a matter is constitutionally ripe for review—in particular, courts may decline to entertain a request for declaratory judgment where the matter is not prudentially ripe. *See In re Combustion Equip. Ass'n Inc. v. EPA*, 838 F.2d 35, 37 (2d. Cir. 1988); *Vullo v. Off. of the Comptroller of the Currency*, 378 F. Supp. 3d 271, 283 (S.D.N.Y. 2019). Prudential ripeness is especially relevant where, as here, a plaintiff challenges an agency action prior to an enforcement action or adjudication. *See Vullo*, 378 F. Supp. 3d at 283.

Prudential ripeness is based on a two-part inquiry: (1) the fitness of the issues for judicial decision; and (2) the hardship to the parties of withholding court consideration. *See Vullo*, 378 F. Supp. 3d at 283 (citation omitted). An issue is not fit for adjudication if, on balance, the Court's analysis is contingent on future events that may or may not occur. *See In re Combustion Equip. Assoc., Inc.*, 838 F.2d at 39; *TNB USA Inc. v. Fed. Reserve Bank of New York*, No. 1:18-CV-7978 (ALC), 2020 WL 1445806, at *9-10 (S.D.N.Y. Mar. 25, 2020) (citation omitted). More specifically, courts determine whether a dispute is fit for judicial review by weighing whether: "(1) the disputed agency decision is final; and (2) whether the issue is purely legal or the underlying legal issues would be facilitated if they were raised in the context of a specific attempt to enforce regulations." *In re Combustion*, 838 F.2d at 38. In particular, suits seeking

declaratory relief that are "based on potential future events are ill-suited for declaratory relief." *See Greater New York Hosp. Ass'n v United States*, No. 98 CIV. 2741 (RLC), 1999 WL 1021561, at *9 (S.D.N.Y. Nov. 9, 1999) (citation omitted).

If a case is constitutionally and prudentially ripe, courts look to the following factors in determining whether to entertain a request for declaratory relief:

> (1) whether the judgment will serve a useful purpose in clarifying or settling the legal issues involved; . . . (2) whether a judgment would finalize the controversy and offer relief from uncertainty . . . [3] whether the proposed remedy is being used merely for procedural fencing or a race to res judicata; [4] whether the use of a declaratory judgment would increase friction between sovereign legal systems or improperly encroach on the domain of a state or foreign court; and [5] whether there is a better or more effective remedy."

Dow Jones & Co., 346 F.3d at 359-60; *see also Grand Trunk W. R.R. Co. v. Consol. Rail Corp.*, 746 F.2d 323, 326 (6th Cir. 1984).

II. Pfizer Is Not Entitled to a Declaratory Judgment that Either of Its Proposed Programs Would Pass Muster Under the AKS; and Defendants Are Entitled to Dismissal or Summary Judgment on These Claims

A. OIG Appropriately Concluded that Pfizer's Direct Subsidy Program Would Violate the AKS if Implemented with the Requisite Intent

Because OIG's Advisory Opinion correctly applied the AKS in concluding that Pfizer's proposed Direct Subsidy Program would violate that law if implemented with the requisite intent —a conclusion supported by the administrative record—Pfizer is not entitled to a declaratory judgment holding the opposite, which would effectively immunize its implementation of the program. For the same reasons, the Government is entitled to summary judgment on this claim.

Pfizer's Direct Subsidy Program falls squarely within the ambit of the AKS.[4] The program would directly provide remuneration to Medicare Part D patients for the purpose of

[4] Pfizer concedes that, as OIG concluded (AR 156), none of the AKS's statutory exceptions or regulatory safe harbors applies; indeed, Pfizer does not even cite the exceptions or safe harbors in its brief, *see* 42 U.S.C. § 1320a-7b(b)(3); 42 C.F.R. § 1001.952.

purchasing tafamidis. And Pfizer concedes that the chief purpose of the program is to cause Medicare patients to purchase tafamidis who otherwise would not do so, given Pfizer's steep pricing of the drug. *See* AR 144-45 n.8 ("[T]he principal reason that patients would not fill their prescriptions [for tafamidis] is the inability to pay their out-of-pocket costs . . . ."); *see also* Compl. ¶ 7. Accordingly, OIG appropriately concluded in the Advisory Opinion that the Direct Subsidy Program is "highly suspect under the [AKS]." AR 156. To argue the opposite, Pfizer misreads the AKS in a number of ways that the Court should reject.

1. The AKS Does Not Require "Corrupt Intent"

Pfizer effectively asks this Court to amend the AKS by inserting the word "corruptly" before "induce." *See, e.g.*, Pl. Mot. at 9 (asserting AKS only reaches "quid-pro-quo payments paid to corrupt or otherwise improperly exercise influence over the recipient's judgment"); *see also id.* at 10-12. The AKS contains no such limiting term. Indeed, if the AKS only reached "corrupt" inducements, there would be no need for Congress to provide statutory safe harbors, such as "pa[yment] by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services," 42 U.S.C. § 1320a-7b(b)(3)(B), nor to grant HHS the authority to establish additional regulatory safe harbors, *see* 42 U.S.C. § 1320a-7d(a)—which HHS has done, *see* 42 C.F.R. § 1001.952.

Courts have long interpreted the AKS according to its plain language. "[T]his Court and others within this District follow the rule of the Third, Fifth, Seven, Ninth, and Tenth Circuits: that the [Government] need only prove that 'one purpose' of [the] remuneration is to induce a person to use a service for which payment is made under a federal health care program." *United States v. TEVA Pharm. USA, Inc.*, No. 13 Civ. 3702 (CM), 2016 WL 750720, at *17 (S.D.N.Y. Feb. 22, 2016) (internal quotation marks omitted); *accord Dhaliwal v. Salix Pharm., Ltd.*, 752 F.

App'x 99, 100 (2d Cir. 2019). The Advisory Opinion correctly recites this standard. AR 150.

Indeed, Pfizer can point to no case in which a court has held that the AKS is limited to "corrupt" inducements. Instead, Pfizer bases its chief argument on a misreading of a sentence in a single inapposite case concerning an entirely different statute, 18 U.S.C. § 201, which prohibits the bribery of public officials and witnesses. *See* Pl. Mot. 10 (citing *United States v. Alfisi*, 308 F.3d 144, 149 (2d Cir. 2002)). That statute—unlike the AKS—includes the word "corruptly" (four times), which is why the Second Circuit notes in *Alfisi* that the statute requires proof of "corrupt intent." *See* 18 U.S.C. § 201(b); *Alfisi*, 308 F.3d at 149.

Pfizer also incorrectly characterizes *Alfisi* as recognizing that a *quid pro quo* necessarily involves a corrupt intent. *See* Pl. Mot. at 10. In fact, the inverse is true: the Second Circuit in *Alfisi* construes the "corrupt intent" expressly required by this unrelated statute, 18 U.S.C. § 201, simply to require proof of a *quid pro quo*. *See Alfisi*, 308 F.3d at 149. In the context of 18 U.S.C. § 201, this is obvious: offering a public official something of value in exchange for an official act is, in and of itself, corrupt. *Alfisi* nowhere suggests that a *quid pro quo* in the context of any other statute must include "corrupt intent" to satisfy that other statute's requirements.

In passing, Pfizer quotes *TEVA* out of context for the proposition that "an 'inducement' under the AKS must be made for 'improper purposes.'" *Id.* (quoting *TEVA*, 2016 WL 750720, at *17); *see* Pl. Mot. at 11. To the contrary, *TEVA* underscores the established principle—expressed in the Advisory Opinion—that to prove an AKS claim, the government "need only prove that 'one purpose' of the remuneration is to induce a person to use a service for which payment is made under a federal health care program.'" *TEVA*, 2016 WL 750720, at *17. In the course of rejecting the pharmaceutical defendants' argument that their speaker programs were not alleged to have "had any single *universal* purpose," the *TEVA* court notes that these programs

were allegedly "a means to provide money to doctors who prescribed large amounts of the Drugs" and so "Relators have done all they must at the pleading stage to advance a theory that the speaker program had a universal and improper purpose." *Id.* The "improper purpose" to which the Court refers in *TEVA* is simply the "purpose . . . to induce a person to use a [covered] service." *Id.* Such a purpose is "improper," when coupled with remuneration, because offering or providing remuneration with the intent to induce a covered purchase violates the AKS. No additional showing of a "corrupt" purpose is required.[5]

To "buttress" its misreading of *Alfisi*, Pfizer points to a different AKS provision establishing liability for the solicitation or receipt of remuneration "in return for" referring for purchase or purchasing a covered good or service. *See* Pl. Mot. at 11 (citing 42 U.S.C. § 1320a-7b(b)(1)). Pfizer's conclusory assertion notwithstanding, it is difficult to see how this language establishes that some additional showing of "corruption" is required for liability under paragraph (b)(1), let alone the paragraph at issue here, (b)(2), which does not include the phrase "in return for." Pfizer appears to conflate the question of whether a *quid pro quo* is required with the entirely separate question of whether some additional "corrupt intent" is required under the AKS.

Pfizer also attempts to argue that "remuneration" should be read narrowly to refer only to "kickbacks" and "bribes."[6] Pl. Mot. at 11-12. But it is well settled that "remuneration" under

[5] Pfizer also quotes *Guilfoile v. Shields*, which refers to "the use of payments to improperly influence decisions on the provision of health care that lead to claims for payment to federal health care programs." 913 F.3d 178, 192-93 (1st Cir. 2019); *see* Pl. Mot. at 11. The First Circuit's characterization of such influence as "improper[]" appears to be a simple recognition, per the AKS, that *any* "influence [on] decisions on the provision of health care" from remuneration provided for that purpose is improper.

[6] Pfizer even argues that the term "rebate" should be read to mean "kickback" or "bribe" per the principle of *nosciitur a sociis*. *See* Pl. Mot. at 12 n.11. In fact, that rule of construction—which only applies where the meaning is ambiguous, which is not the case here—would have the Court read "any remuneration [offered or paid] . . . directly or indirectly, overtly or covertly, in cash or

the AKS encompasses "anything of value in any form whatsoever." *Dhaliwal v. Salix Pharm., Ltd.*, 752 F. App'x 99, 100 (2d Cir. 2019). Indeed, Congress amended the AKS in 1977 to expand its scope from "kickbacks" to "any remuneration (including any kickback, bribe, or rebate)." 42 U.S.C. § 1320a-7b(b). Especially relevant here, courts have repeatedly recognized that copay assistance constitutes "remuneration" under the AKS. *See, e.g.*, *United States ex rel. Grenadyor v. Ukrainian Vill. Pharm., Inc.*, 772 F.3d 1102, 1104 (7th Cir. 2014); *United States ex rel. STF, LLC v. Vibrant America, LLC*, No. 16 Civ. 2487, 2020 WL 4818706, at *13 (N.D. Cal. Aug. 19, 2020); *United States ex rel. Goodman v. Arriva Med., LLC*, No. 13 Civ. 760, 2020 WL 3840446, at *2 (M.D. Tenn. July 8, 2020); *United States ex rel. Strunck v. Mallinckrodt ARD, LLC*, Nos. 12 Civ. 175, 13 Civ. 1776, 2020 WL 362717, at *4 (E.D. Pa. Jan. 22, 2020).

Pfizer next inaccurately describes an exception in the BIS for certain cost-sharing waivers and draws an erroneous parallel between that exception and an exception in the AKS that narrowly excludes from the definition of "remuneration" cost-sharing waivers by pharmacies, but not by manufacturers like Pfizer. Pl. Mot. at 13. This narrowly drawn exception cuts against Pfizer's arguments, showing that Congress knew how to make exceptions when it wished to do so and chose to limit this exception to pharmacy waivers.

Finally, Pfizer falls back on the rule of lenity, Pl. Mot. at 13, but that "is a tool of last resort reserved for cases where, 'after seizing every thing [sic] from which aid can be derived, the Court is left with an ambiguous statute.'" *United States v. Tabb*, 949 F.3d 81, 89 n.8 (2d Cir.

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in kind" as broadly as it is written, to encompass not only "kickbacks" and "bribes" but also "rebates." 42 U.S.C. § 1320a-7b(b)(2). In any case, even if this provision were ambiguous, deference should be given to the agency's long-standing interpretation that the term "remuneration" covers anything of value in any form or manner whatsoever. *See, e.g.*, *Aleutian Capital Partners, LLC v. Scalia*, 975 F.3d 220, 231 (2d Cir. 2020) (applying *Chevron* deference to resolve statutory ambiguity in favor of agency's interpretation).

2020) (citation omitted). Because it is unambiguous that the plain language of the AKS encompasses Pfizer's proposed Direct Subsidy Program, the rule does not apply. In any case, the rule of lenity does not permit courts to amend statutes by inserting new words, as Pfizer asks the Court do to here with the word "corruptly."

2. The AKS Does Not Require Evidence of a *Quid Pro Quo*

Pfizer also repeatedly asserts that the AKS requires proof of a *quid pro quo*. *See* Pl. Mot. at 9-12. Pfizer is incorrect for the reasons stated below, but, in any event, as OIG correctly identified in the Advisory Opinion, Pfizer's Direct Subsidy Program clearly would establish a *quid pro quo*. AR 154. Under the program, a Part D beneficiary would receive Pfizer's subsidy benefit only if the beneficiary purchases tafamidis; Pfizer is not proposing to provide funds to all ATTM-CR patients for the purchase of any drug (including a competitor's drug prescribed off-label) or any non-pharmaceutical therapy. Put another way, in exchange for purchasing Pfizer's drug, Pfizer would provide the Part D beneficiary a subsidy, with the intent to induce that beneficiary to purchase tafamidis. *See* AR 144-45 n.8.

More fundamentally, Pfizer is wrong that the AKS requires a *quid pro quo* arrangement. Courts have repeatedly held that an inducement need not be successful in "actually influenc[ing] a patient's or medical professional's judgment" to violate the AKS. *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 96-97 (3d Cir. 2018). As a court in this district held recently, "[b]ecause intent is all that is required, it does not matter whether a particular referral [generates] results," and "[t]hus, the statute does not require evidence of a '*quid pro quo*' in the sense that each bribe must successfully generate referrals." *United States v. TEVA Pharm. USA, Inc.*, No. 13 Civ. 3702 (CM), 2019 WL 1245656, at *10 (S.D.N.Y. Feb. 27, 2019) (internal quotation marks omitted); *accord United States ex rel. Kester v. Novartis Pharm.*

Corp., 23 F. Supp. 3d 242, 263 (S.D.N.Y. 2014).

Pfizer cites no case to the contrary. Rather, Pfizer relies on *United States v. Krikheli*, 461 F. App'x 7, 10-11 (2d Cir. 2012), in which this question was not presented. In rejecting criminal defendants' challenge on appeal to a jury instruction in a case that involved *quid pro quo* transactions,[7] the *Krikheli* court noted that the instructions, which included a reference to *quid pro quos*, "accurately described the law and assuaged defendants' concern that they not be convicted simply for paying middlemen to recommend [certain] services to physicians who would make independent referral decisions . . . ." *Id.* at 11. The Second Circuit has never held that liability under the AKS requires proof of a *quid pro quo*. In any case, because Pfizer's proposed Direct Subsidy program *does* entail a *quid pro quo*, the Court need not reach this question to decide the instant cross-motions for summary judgment.

3. Pfizer's Direct Subsidy Program Would Undermine a Fundamental Feature of the Medicare Part D Benefit

The relief Pfizer seeks—a judgment that implementation of its Direct Subsidy Program would not violate the AKS—would undermine the statutory scheme Congress erected for the Medicare Part D prescription drug benefit. *See* AR 157-60. While private insurers negotiate the price of drugs with pharmaceutical companies, Congress chose instead to incorporate patient cost-sharing obligations into Part D. *See* 42 U.S.C. § 1395w-102(b). One of the chief functions of cost sharing is to help control drug prices by exposing beneficiaries to the economic effects of those prices, incentivizing pharmaceutical companies to reasonably price their drugs. *See* AR 152-53 n.42. If the AKS were construed to permit pharmaceutical companies to freely establish

[7] Notably, this challenge in *Krikheli* concerned the instructions for charges under the AKS's paragraph (b)(1)(B)—which prohibits one from soliciting or receiving remuneration "in return for" purchasing or recommending covered medical care—as well as under the paragraph at issue here, (b)(2)(A), which does not include the "in return for" language.

programs like Pfizer's Direct Subsidy Program, virtually eliminating cost sharing for the vast majority of Part D beneficiaries while leaving Medicare to pay the balance of unchecked drug prices, a key pricing control Congress built into Part D would be destroyed. *See, e.g.*, *U.S. ex rel. Grenadyor*, 772 F.3d at 1104-05 ("a discount or refund" that "reduces a product's cost to the consumer . . . can become a 'kickback'" that "artificially inflates the price that the government pays . . . for prescription drugs for Medicare or Medicaid beneficiaries"). Such a judgment would create an incentive for pharmaceutical companies to set astronomical prices for drugs without affecting demand among Part D beneficiaries—who would be insulated from the economic effects of those price hikes—knowing that Medicare would pick up the tab. *Cf. U.S. ex rel. Strunck v. Mallinckrodt Ard LLC*, 2020 WL 362717, at *2, 4 (explaining how defendant manufacturer allegedly increased the price of a multiple sclerosis drug from $50 to more than $32,200 per vial, "pric[ing] itself out of the market for MS treatment" until defendant established "copay assistance funds" that allowed defendant "to market [its drug] as free to doctors and patients, regardless of its actual, exorbitant price" to the government).

4. Pfizer's Direct Subsidy Program Also Present Risks of Patient Steering, Lock-in, and Broader Anti-Competitive Effects

Finally, OIG correctly concluded in the Advisory Opinion that Pfizer's Direct Subsidy Program "presents many of the traditional risks of fraud and abuse that the [AKS] is designed to prevent." AR 156. In particular, Pfizer's program could "have the practical effect of steering beneficiaries to, and locking them into, [tafamidis]." *Id.* 160-61. As Pfizer acknowledged to OIG, tafamidis is not the only drug prescribed for ATTR-CM; two other medications are prescribed off-label, and a third is the subject of a Phase 3 trial. AR 143-44. In making tafamidis virtually free for the vast majority of Part D beneficiaries, Pfizer's Direct Subsidy Program "could inappropriately divert many [patients] from any other treatment option—now or

in the future." AR 162. Indeed, OIG recognized that the Direct Subsidy Program "shares many of the risky features of problematic seeding programs insofar as it would steer patients to [tafamidis] now so that these beneficiaries would continue to purchase [tafamidis] in the future, even if other FDA-approved therapies emerge." *Id.* Because Pfizer's proposed program "would give a financial advantage to [tafamidis] over competing treatments," it could also have broader anti-competitive effects that might dissuade potential competitors from entering the market. *Id.* Thus, OIG reasonably concluded in the Advisory Opinion that the Direct Subsidy Program would present substantial risks of fraud and abuse of the sort the AKS was designed to curb. AR 156-64.

Thus, the Court should deny Pfizer's request for a declaratory judgment that its Direct Subsidy Program would not violate the AKS. In addition, because OIG's Advisory Opinion is not arbitrary or capricious or otherwise contrary to law, the Court should grant summary judgment to the Government with respect to Pfizer's APA challenge to the Advisory Opinion.

B. The Court Should Not Issue a Declaratory Judgment Blessing the Indirect Subsidy Program

Nor should the Court issue a declaratory judgment that Pfizer's Indirect Subsidy Program passes muster under the AKS. *See* Pl. Mot. at 19-21. First, this claim should be dismissed under Rule 12(b)(1), because the Court lacks jurisdiction to entertain it. As already explained, the only agency action that OIG took with respect to the Indirect Subsidy Program was rejecting Pfizer's June 2019 request for an advisory opinion regarding that program, because "[t]he same, or substantially the same, course of action is under investigation, or is or has been the subject of a proceeding involving HHS or another governmental agency." AR 725, 726; *see supra* Part C (Background). Pfizer does not claim that OIG's rejection of Pfizer's advisory opinion request on this ground—as *required* by 42 C.F.R. § 1008.15(c)(2)—violated the APA, or was *ultra vires* or

otherwise improper, and Defendants are therefore entitled to summary judgment on this claim. In the absence of any APA challenge by Pfizer to the only agency action that OIG actually took with respect to the Indirect Subsidy Program, Pfizer has no other cause of action relating to OIG's conduct on that issue over which the Court may assert jurisdiction. Pfizer claims that it is "proceed[ing] primarily under the Declaratory Judgment Act," with "alternative claims" under the APA, *see* Pl. Mot. at 8 n.9, but as explained above, the Declaratory Judgment Act neither gives rise to an independent cause of action, nor provides a basis for the Court's jurisdiction. *See supra* Part I.C. The Court has no jurisdiction, therefore, to entertain a free-standing request by Pfizer—divorced from an APA-based challenge to any final agency action by OIG—to simply opine on the legality of its Indirect Subsidy Program.

Pfizer also cannot argue that the Court has jurisdiction over this claim on the theory that there exists a sufficiently live controversy, or that Pfizer is imminently subject to threatened enforcement by OIG. *See* Pl. Mot. at 7-8. None of the cases cited by Pfizer for this proposition, *id.*, stands for the proposition that a party may seek a declaratory judgment in the absence of any underlying cause of action over which the court has jurisdiction. Here, Pfizer has no cause of action underlying its request for a declaratory judgment blessing the Indirect Subsidy Program, and there is also no live dispute regarding that program, because OIG has provided no advisory opinion evaluating that program under the AKS. Pfizer cites the 2005 and 2014 Bulletins, *see id.* at 19-20, but those documents simply provide non-binding guidance to the industry as a whole and are not directed at any Pfizer proposal. (Even if it were challenging those Bulletins, Pfizer would be out of time to do so under the APA, *see* 28 U.S.C. § 2401(a).) There is no substantial controversy between the parties simply because OIG was prohibited by regulation from accepting Pfizer's request for an advisory opinion on its Indirect Subsidy Program. That

rejection is not, in itself, preventing Pfizer from doing anything it wishes to do—Pfizer is not *required* to seek or obtain an advisory opinion from OIG before it implements any program—nor does that rejection constitute a threat of enforcement regarding Pfizer's proposed program. There is no basis for the Court to, in a void and simultaneously with other government agencies' proceedings on the same issues, simply sign on to Pfizer's cursory arguments on this issue.

Even if the Court had jurisdiction over Pfizer's claim that its Indirect Subsidy Program passes muster under the AKS, Pfizer has failed to show that it is entitled to summary judgment on that claim. Pfizer devotes a scant two pages of its brief to this argument, *see* Pl. Mot. at 19-21, and points mainly to "the same reasons explained . . . with regard to" the Direct Subsidy Program. *Id.* at 19. As discussed thoroughly above, Pfizer's objections to OIG's AKS analysis in the Advisory Opinion are meritless, *see supra* Part II.A, and are equally groundless as applied to Pfizer's Indirect Subsidy Program. For example, Pfizer's assertion that the AKS is limited to "corrupt or improper" inducements is just as baseless when applied to indirect payments to patients through intermediaries (*e.g.*, independent foundations). *See* Pl. Mot. at 9. Indirect payments to patients through intermediaries qualify as remuneration under the AKS. *See* 42 U.S.C. § 1320a-7b(b)(2); *United States ex rel. Banigan v. Organon USA Inc.*, No. CV 07-12153-RWZ, 2016 WL 10704126, at *3 n.8 (D. Mass. Aug. 23, 2016). More to the point, cost-sharing subsidies, whether direct or indirect, constitute remuneration that may violate the AKS if the requisite intent to induce the purchase of federally reimbursable items or services is present. *See United States ex rel. Grenadyor*, 772 F.3d at 1104. In short, the Court should: (1) deny summary judgment to Pfizer on this claim; and (2) grant Defendants' motion to dismiss this claim for lack of subject-matter jurisdiction; or (3) alternatively, grant summary judgment to Defendants with respect to OIG's rejection of Pfizer's original request for an advisory opinion.

C. If the Court Were to Find APA Violations, It Should Remand

Finally, even if the Court were to find (which it should not) that Defendants somehow violated the APA in connection with OIG's rejection of Pfizer's original advisory opinion request and issuance of the Advisory Opinion, the appropriate remedy would be remand, not issuance of declaratory judgments opining that both of Pfizer's proposed programs are legal under the AKS. As discussed above, remand is the "usual" remedy under the APA, and courts "traditionally have been reluctant" to issue declaratory judgments regarding challenged administrative determinations, "unless [they] arise in the context of a controversy 'ripe' for judicial resolution." *See Abbott Labs.*, 387 U.S. at 148; *see supra* Parts I.B.2, C.

Here, both proposed programs are, at least, prudentially unripe for adjudication via declaratory judgments. Under the first prudential ripeness prong, an issue is not fit for adjudication if the court's analysis is contingent on future events that may or may not occur, which a court may ascertain by weighing whether: (1) the disputed agency decision is final; and (2) whether the issue is purely legal or the underlying legal issues would be "facilitated if they were raised in the context of a specific attempt to enforce regulations." *In re Combustion*, 838 F.2d at 37-39; *see also, e.g.*, *TNB USA Inc.*, 2020 WL 1445806, at *9-10.

Both of Pfizer's proposed programs would be much better considered in the context of a specific enforcement action. Indeed, neither program has even been implemented yet, and OIG made clear with respect to the Direct Subsidy Program that "[a]ny definitive conclusion regarding the existence of an [AKS] violation requires consideration of all of the facts and circumstances of the arrangement as implemented." AR 142.

Pfizer's Indirect Subsidy Program is even more ill-suited for adjudication. Pfizer's proposal has only been described within Pfizer's rejected original request for an advisory opinion, AR 746, 757, was not fleshed out through supplemental submissions to or discussions

with OIG, and has never been substantively examined by the agency. Furthermore, nothing prohibits Pfizer from donating to foundations in a manner that does not violate the AKS or its CIA. The 2005 Bulletin, for example, advises that notwithstanding the applicability of the AKS to payments by pharmaceutical manufacturers to patients via foundations, "pharmaceutical manufacturers can donate to *bona fide* independent charity [PAPs], provided appropriate safeguards exist."[8] 70 Fed. Reg. at 70,623-24. The Court lacks enough information, however, to assess how Pfizer's hypothetical Indirect Subsidy Program would, for example, avoid functioning "as a conduit for payments by the pharmaceutical manufacturer to patients." *Id*. at 70626, 70627. Pfizer's claim regarding its Indirect Subsidy Program is not fit for review.

The second prudential ripeness factor—the hardship to the parties of withholding court consideration, *see Vullo*, 378 F. Supp. 3d at 283—similarly weighs against issuing declaratory judgments respecting Pfizer's proposed programs. For the reasons discussed above, Pfizer is simply not under any sufficiently imminent threat of an enforcement action with respect to either proposed program, as OIG has withheld definitive judgment in the absence of actual implementation of the Direct Subsidy Program, and has offered no opinion at all as to the Indirect Subsidy Program. If the Court were to find any APA violation with respect to OIG's actions as to either proposed program, no urgent circumstance would compel the Court to impose the unusual remedy of immunizing the proposed program via a declaratory judgment that the program would be legal under the AKS.

Moreover, as to the Indirect Subsidy Program, it bears repeating that Pfizer is *already subject* to the 2018 CIA it executed in relation to allegations that Pfizer improperly used an

[8] Indeed, Pfizer admits that there are existing foundations with funds that cover several diseases, including ATTR-CM. Compl. ¶ 120.

independent foundation as "a conduit to pay the co-pay obligations of Medicare patients taking three Pfizer drugs." *See* AR 480–81. Under the 2018 CIA, Pfizer is required to, among other things, refrain for five years from influencing, directly or indirectly, an independent foundation's PAP operations, and from donating to a disease state fund that covers only a single product or only Pfizer's products. AR 514. Pfizer does not deny that under the 2018 CIA, it is "obligated to comply with" what it terms "OIG's lawful guidance documents." Pl. Mot. at 8 n.8; *see also, e.g.*, AR 490 (provision of 2018 CIA requiring Pfizer to implement written policies and procedures "designed to ensure that Pfizer's arrangements and interactions . . . comply with all guidance issued by OIG relating to the support and funding of patient assistance programs, including but not limited to" the 2005 Bulletin and the 2014 Bulletin). Yet, in the rejected advisory opinion request for the Indirect Subsidy Program, Pfizer stated its desire to "communicate and collaborate" with a foundation to "define the fund" as one that would be restricted to patients with ATTR-CM. AR 746. Remarkably, Pfizer makes no bones about asking this Court to wade into an area in which the company is currently subject to legal restriction, to explicitly permit Pfizer to carve out from the 2018 CIA (and immunize) the Indirect Subsidy Program—before it has even been implemented.

If Pfizer wished to challenge the application of the AKS to an indirect subsidy program, it could have done so in the context of the prior enforcement action that gave rise to the 2018 CIA—in other words, in the context of "a specific attempt to enforce regulations." *In re Combustion*, 838 F.2d at 37-39. If the Court were to accede to Pfizer's demand here to issue preemptive declaratory judgments on the legality of Pfizer's proposed programs, however, the Court would impose more than one hardship on the Government. The Court would undermine OIG's ability to enforce the 2018 CIA, as well as several other in-force CIAs with manufacturers

containing provisions substantially similar to the above-cited provisions. *See, e.g.*, *https://oig.hhs.gov/fraud/cia/agreements/Novartis_Corporation_06302020.pdf* (last visited November 16, 2020). Additionally, such a ruling may invite parties to other current and future CIAs, which are subject to extensive negotiations, to challenge the terms of their CIAs. The Court would also effectively usurp OIG's role in issuing technical and consistent guidance to the industry regarding the AKS; and interfere with the ability and discretion of the Government to assess various PAP arrangements as implemented, and the appropriateness of AKS enforcement actions on a case-by-case basis. *See, e.g.*, *Greater New York Hosp. Ass'n*, 1999 WL 1021561, at *8-9 (declining to enter a declaratory judgment and finding clear hardship to OIG because the proposed judgment would prevent OIG from pursuing its statutory mandate to investigate fraud and police the spending of Medicare funds). These hardships strongly counsel against issuing the declaratory judgments that Pfizer seeks.

III. Pfizer's Constitutional Claims Should Be Dismissed

A. Pfizer Is Not Entitled to a Declaration that Some Future OIG Interpretation of the AKS as Applied to the Indirect Subsidy Program Would Violate Pfizer's First Amendment Rights

Pfizer seeks a declaratory judgment that "[i]f OIG prevented the Proposed Independent Charity Program, it would infringe on Pfizer's First Amendment right to engage in speech incident to charitable giving and would impose impermissible speaker-based restrictions on Pfizer as a pharmaceutical manufacturer." Compl. ¶ 146; *see also* Pl. Mot. at 21. Pfizer is inviting the Court to decide an issue that is not actually presented by this case. In other words, the claim is constitutionally unripe. Pfizer also lacks standing to raise this claim, which is also prudentially unripe. There are other defects in Pfizer's claim, all of which support its dismissal.

Pfizer's First Amendment claim should, first, be dismissed under Rule 12(b)(1) as constitutionally unripe. "The constitutional requirement of ripeness derives from Article III's

limitation of federal jurisdiction to live cases or controversies." *United States v. Ayers*, 371 F. App'x 162, 163 (2d Cir. 2010). But a claim is not ripe if it depends on "contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United State*s, 523 U.S. 296, 300 (1998). Pfizer's claim depends on just such a contingent future event that may never occur, namely, the issuance of an unfavorable advisory opinion to Pfizer regarding an Indirect Subsidy Program like the one that Pfizer proposed in June 2019. AR 33.

As noted above, OIG has made no decision regarding the merits of Pfizer's Indirect Subsidy Program, *i.e.*, no decision regarding whether, after reviewing the facts and circumstances, a favorable or unfavorable advisory opinion is warranted. Thus, contrary to Pfizer's suggestion, OIG has not concluded in an advisory opinion that Pfizer is "prohibit[ed]" from making donations to independent foundations or from conferring about "shared charitable goals." *See* Pl. Mot. at 21. Indeed, OIG may never issue an actionable decision to Pfizer on a proposed program like the one described in Pfizer's original advisory opinion request. For one thing, Pfizer may not again seek an advisory opinion on a proposed program relating to tafamidis. If it does, 42 C.F.R. § 1008.15(c)(2) may still be applicable, meaning that, again, OIG would not be able to issue an opinion that Pfizer contends *might* be constitutionally problematic. Finally, even if OIG were to issue an advisory opinion, it might not be unfavorable: The opinion would depend on the specific facts and circumstances of the proposed program as presented and certified by Pfizer to OIG during the advisory opinion process.

For similar reasons, Pfizer also lacks standing to raise this claim. To establish standing, a plaintiff must be able to secure meaningful relief from the Court. *Lujan*, 504 U.S. at 561. Pfizer cannot do so here. Even if the Court were to conclude that OIG has expressed views incompatible with the First Amendment in the 2005 Bulletin or elsewhere, that would not be

likely to redress Pfizer's injuries relating to its Indirect Subsidy Program, because 42 C.F.R. § 1008.15(c)(2) (which is not speech-related) prohibited OIG, for procedural reasons, from accepting Pfizer's request to issue an advisory opinion. *See "Q"-Lungian Enters., Inc. v. Town of Windsor Locks*, 272 F. Supp. 3d 289, 295 (D. Conn. 2017) ("If a plaintiff challenges a law that forbids certain conduct when that very same conduct is also prohibited by a separate law that the plaintiff has not challenged, then a plaintiff lacks standing.").

Pfizer also lacks standing to assert its First Amendment claim because it has already agreed, in the 2018 CIA, not to engage in the conduct that it seeks to have this Court sanction. AR 501-502. In short, Pfizer's requested declaratory judgment that the application of OIG's guidance to its "proposed independent charity program would violate the First Amendment," *see* Compl. ¶¶ 144-50, would provide it no relief because it has knowingly and voluntarily waived its right to engage in that very same conduct. Because the settlement relating to the 2018 CIA centered on allegations that Pfizer improperly used an independent foundation as "a conduit to pay the co-pay obligations of Medicare patients taking three Pfizer drugs," *see* AR 480-81, Pfizer agreed in the 2018 CIA that it would only donate to such an independent foundation's patient assistance programs if it refrained from, among other things, exerting "any influence or control over the identification, delineation, establishment, or modification of any specific disease funds" operated by the foundation. AR 501. Pfizer further agreed not to make "suggestions or requests to the [foundation] about the identification, delineation, establishment, or modification of disease state funds." *Id*. Nonetheless, Pfizer requested from OIG an advisory opinion that would allow it to provide financial assistance to patients prescribed tafamidis by "funding an existing independent charity." *See* Compl. ¶ 8. In particular, it proposed to communicate and collaborate with an existing independent foundation to define a disease fund for ATTR-CM patients and

ensure that it would be funded. *See* AR 757.

As noted above, Pfizer now seeks to execute an end-run around the advisory opinion process and the terms of the 2018 CIA to obtain the Court's preemptive blessing of its Indirect Subsidy Program. But even putting that issue aside, a declaratory judgment authorizing Pfizer to engage in conduct that it has already agreed not to engage in would provide Pfizer no redress. The 2018 CIA bars the conduct that Pfizer seeks to have approved here, and Pfizer does not challenge the 2018 CIA in this lawsuit;[9] Pfizer thus lacks standing to pursue this claim because any favorable judgment would not redress its supposed injury. *See, e.g.*, *Stauffer v. Brooks Bros. Grp., Inc.*, 758 F.3d 1314, 1320 (Fed. Cir. 2014) (no standing where "independent legal provisions bar a claim and only one provision is at issue").

Even if the Court somehow concludes, which it should not do, that Pfizer has standing to assert its First Amendment claim and that the claim is constitutionally ripe, the Court should nevertheless invoke the prudential ripeness doctrine to decline to reach the claim. "Prudential ripeness is … a tool that courts may use to enhance the accuracy of their decisions and to avoid becoming embroiled in adjudications that may later turn out to be unnecessary or may require premature examination of, especially, constitutional issues that time may make easier or less controversial." *Simmonds v. INS*, 326 F.3d 351, 357 (2d Cir. 2003). Under the hardship prong of the prudential ripeness test, *see supra* Parts I.C, II.C, the question is whether the claim addresses a "direct and immediate dilemma for the parties." Here, it does not. Even if the Court decided that Pfizer's interpretation of the First Amendment were correct, nothing would change for Pfizer. OIG simply cannot be required to issue an advisory opinion in contravention of 42

[9] A party can bargain away its First Amendment rights "voluntarily, knowingly, and intelligently," *Legal Aid Soc'y v. City of New York*, 114 F. Supp. 2d 204, 227 (S.D.N.Y. 2000).

C.F.R. § 1008.15(c)(2). Nor is the issue fit for decision; as already discussed, Pfizer's First Amendment claim is contingent on future events, which may never occur.

Pfizer may attempt to frame its First Amendment claim in terms of the guidance issued in the 2005 Bulletin, but this argument would fail for a number of threshold reasons. First, Pfizer would lack standing to challenge the 2005 Bulletin. This is so because the Court could not award Pfizer meaningful relief for two reasons: (1) 42 C.F.R. § 1008.15(c)(2) prevented OIG from issuing an advisory opinion, regardless of what the 2005 Bulletin says; and (2) the 2005 Bulletin simply conveys OIG's non-binding views regarding how binding statutes and regulations may apply in different circumstances. Even without the 2005 Bulletin, those statutes and regulations would still apply in the same way. Second, any challenge to the 2005 Bulletin would be prudentially unripe: As any decision on the 2005 Bulletin would have no real-world impact on Pfizer at this time (due to the effect of 42 C.F.R. § 1008.15(c)(2) and the nature of the Bulletin), the Court would be unnecessarily resolving a constitutional question. *See Simmonds*, 326 F.3d at 357; *Clark v. Martinez*, 543 U.S. 371, 380-81 (2005) (describing constitutional avoidance).

A First Amendment challenge to a prospective unfavorable advisory opinion from OIG on Pfizer's Indirect Subsidy Program, or to the 2005 Bulletin, should also be dismissed under Rule 12(b)(6). OIG, through the advisory opinion process, does not "prohibit" anything; it merely determines whether, as relevant here, a proposed arrangement involves prohibited remuneration and whether the arrangement constitutes grounds for the imposition of sanctions. *See* 63 Fed. Reg. 38,311, 38,317 (July 16, 1998). Particularly where OIG opines, as it did here in the case of the Direct Subsidy Program, that it cannot, without implementation of the arrangement, come to a definitive conclusion regarding whether a proposed program or action

violates the AKS, the requestor can still engage in the proposed course of conduct: It simply does so without prospective administrative immunity already having been granted by OIG.

What is more, the 2005 Bulletin makes clear that pharmaceutical manufacturers *can* donate to foundation-operated PAPs in ways that present a low risk of fraud and abuse (thereby alleviating any First Amendment concerns about a total ban on any such arrangement). For example, the 2005 Bulletin states: "[I]n the circumstances described in this Bulletin, cost-sharing subsidies provided by *bona fide*, independent charities unaffiliated with pharmaceutical manufacturers should not raise anti-kickback concerns, even if the charities receive manufacturer contributions." 70 Fed. Reg. at 70624. And nowhere does the 2005 Bulletin indicate that simply conferring with regard to "shared charitable goals" is problematic. *See* Pl. Mot. at 21. Rather, the 2005 Bulletin simply expresses concern that manufacturers will make "arrangements [that] would present an elevated risk of fraud and abuse because of the increased likelihood that the PAP would function as an improper conduit for manufacturers to provide funds to patients using their specific drugs," which is precisely what Pfizer wants to do—and which implicates the AKS. *See* 70 Fed. Reg. at 70,627; *cf. Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 458 (2d Cir. 2001) (upholding limitation on speech that would facilitate circumvention of copyright law).

B. Pfizer Is Not Entitled to a Declaration that OIG's Interpretation of the AKS With Respect to Pfizer's Proposed Programs Would Violate the Equal Protection Clause of the Fifth Amendment

Last, Pfizer asks the Court to issue a declaratory judgment that denying favorable advisory opinions with respect to Pfizer's proposed programs discriminates against "middle-income Medicare beneficiaries . . . based solely on their socioeconomic status" and thus violates the equal protection component of the Fifth Amendment's Due Process Clause. *See* Pl. Mot. at 24-25; Compl. ¶¶ 151-57. Pfizer claims that OIG's interpretation of the AKS supposedly has the effect of placing tafamidis out of reach for middle-income Medicare beneficiaries, while wealthy

beneficiaries can afford the cost-sharing obligations, and low-income beneficiaries are covered by Medicare's Low Income Subsidy (or Pfizer's own free drug program). Compl. ¶ 13.

This claim should be dismissed under Rule 12(b)(1), because Pfizer lacks standing to raise an equal protection challenge on behalf of unnamed patients. A party cannot ordinarily "rest his claim to relief on the legal rights or interests of third parties." *Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004) (quotation marks omitted). Since Pfizer is not, itself, a middle-income Medicare beneficiary affected by high cost-sharing resulting from the high list price Pfizer set for tafamidis, it lacks standing to raise this claim. Nor has Pfizer anywhere asserted that it is an economically injured vendor that, as such, may assert the "concomitant rights of third parties." *See Craig v. Boren*, 429 U.S. 190, 195 (1976).

The Fifth Amendment claim also fails on the merits, and should therefore be dismissed pursuant to Rule 12(b)(6). "The equal protection component of the Fifth Amendment prohibits only purposeful discrimination." *Harris v. McRae*, 448 U.S. 297, 323 n.26 (1980). It does not provide a basis for disparate impact claims, *id.*, but that is precisely the type of claim that Pfizer appears to raise here. That is, Pfizer does not allege that OIG purposefully discriminated against middle-income beneficiaries. Indeed, OIG has not drawn distinctions among any types of beneficiaries; OIG's views, whether expressed in the Advisory Opinion or 2005 Bulletin, simply analyze the operation of a federal anti-fraud statute against proposed business arrangements, for the purpose of combating fraud and abuse in federal healthcare programs. Pfizer contends that OIG's position regarding the AKS will lead to "unequal results." Compl. ¶ 13. This is an archetypal disparate impact claim that is not cognizable under the Fifth Amendment; and more fundamentally, this contention misplaces the blame. If tafamidis is out of a reach for certain middle-income Medicare beneficiaries, that is due to Pfizer's pricing of tafamidis as the most

expensive cardiovascular drug in history, AR 152; Pfizer's structuring of its free drug program to exclude those beneficiaries; and, more generally, the particular details of the Medicare Part D drug benefit, which Pfizer is not challenging here, as they interact with Pfizer's pricing schemes.

Even if the Court determined that the issuance of the Advisory Opinion somehow constituted a wealth-based distinction, which it did not, Pfizer's equal protection claim still would not survive review. Wealth-based distinctions are subject to rational basis review.[10] *Harris*, 448 U.S. at 323-24. For many of the same reasons discussed at length above, the Advisory Opinion easily satisfies the rational basis standard. The Advisory Opinion concludes based on ample record evidence that Pfizer's Direct Subsidy Program would create a significant risk of fraud and abuse, namely, a significant risk that Pfizer would provide remuneration to patients to induce them to purchase its drugs, in violation of the AKS. *Id.* Declining to provide prospective immunity for practices that present a high risk of fraud and abuse, at the expense of the Medicare Trust Fund, is a rational decision.

[10] Pfizer incorrectly contends that wealth-based restrictions can be subject to strict scrutiny if they result in a complete deprivation of some interest; *see* Pl. Mot. at 24-25; in fact, that would be true only if a fundamental constitutional right were at stake. *See San Antonio Indep. Sch. Dist. v. Rodriguez*, 411 U.S. 1, 29 (1973). But there is no fundamental constitutional right to receive tafamidis. Pfizer relies heavily on *Griffin v. Illinois*, 351 U.S. 12 (1956), but that case does "not explain its holding in terms of either rational basis or strict scrutiny"; rather, *Griffin* turns on the importance of equal access to the courts. *Robinson v. Purkey*, No. 3:17-CV-1263, 2017 WL 4418134, at *7 (M.D. Tenn. Oct. 5, 2017).

CONCLUSION

For the foregoing reasons, the Court should deny Pfizer's motion for summary judgment and grant Defendants' cross-motion to dismiss or for summary judgment.

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